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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/681,302

03/15/2001

Samuel F. Liprie

INE-0044-C1

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02/22/2006

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EXAMINER

GREENE, DANIEL LAWSON

ART UNIT

PAPER NUMBER

3663

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/681,302		LIPRIE, SAMUEL F.	
	Examiner		Art Unit	
	Daniel L. Greene Jr.		3663	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 March 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Allowable Subject Matter

1. Prosecution on the merits of this application is reopened. Claims 1-32 are considered unpatentable because applicants claim for priority is unacceptable. Further, it is noted that an Obvious type Double Patenting rejection is warranted. Any inconvenience to applicant is regretted.
2. Applicant is advised that the Notice of Allowance mailed 7/11/2005 is vacated. If the issue fee has already been paid, applicant may request a refund or request that the fee be credited to a deposit account. However, applicant may wait until the application is either found allowable or held abandoned. If allowed, upon receipt of a new Notice of Allowance, applicant may request that the previously submitted issue fee be applied. If abandoned, applicant may request refund or credit to a specified Deposit Account.

Priority

3. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. However it is noted that application 08/827,787 ('787) does NOT contain the same specification as the instant application, as shown by, for example, comparing the "Field of the Invention" section of '787 with paragraph [0001] of the application, page 4 lines 12+ of '787 do not appear in the instant application, Figure 3 (the elected embodiment) of the instant application is not found in the figures of '787, etc. Accordingly the instant application's priority is only applicable to application 09/455,579, filed 12/06/1999.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the radiation sources must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 14, and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is not seen wherein the specification as filed discloses multiple radioactive sources. It appears the specification only discloses a radioactive core, that is one core, which may be considered a source or one source, not multiple sources. See for examples, paragraphs 7, 8, etc.

6. Claims 1, 14 and 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a radiation source, does not reasonably provide enablement for multiple radiation sources. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. See the discussion of this topic in section 5 above.

7. Claims 1, 14 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 14 and 25 are vague, indefinite and incomplete in what all is meant by and encompassed by the phrase "radiation sources", hence the metes and bounds of the claim are undefined. See the discussion of this topic in section 5 above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-32 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,503,614 ('614) to Liprie.

Liprie discloses applicant's invention as claimed in, for example, figures 1-3, claims 1-38 and the specification.

Note specifically that the instant application's figures, specification and claims appear identical to the figures, specification and claims of '614, however because priority has not been established, it is proper to reject the instant application over '614.

Claims 1, 14 and 25 are disclosed in, for example claims 1 and 6 of '614,

Claims 2 and 15 are disclosed in, for example claim 2 of '614,

Claims 3 and 18 are inherently disclosed in, for example claim 9 of '614 wherein it is understood that in order for the device to function, i.e. for radiation to radiate, the encapsulation material must be permeable,

As to limitations which are considered to be inherent in a reference, note the case law In re Ludtke, 169 USPQ 563, In re Swinehart, 169 USPQ 226, In re Fitzgerald, 205 USPQ 594, In re Best et al, 195 USPQ 430, and In re Brown, 173 USPQ 685,688.

Claims 4 and 19 are disclosed in, for example claim 9 of '614,

Claims 5-7, 16 and 26 are disclosed in, for example claims 4,10 of '614, etc.

Claims 8, 17 and 27 are disclosed in, for example Figure 3 of '614,

Claims 9, 11, 20, 21, 28 and 29 are disclosed in, for example Figures 1-3 of '614,

Claims 10, 22 and 30 are disclosed in, for example claims 7 and 8 of '614,

Claims 12, 13, 23, 24, 31 and 32 are disclosed in, for example claims 16 and 17 of '614,

Double Patenting

9. If applicant believes he has priority back to patent '614, then the following double patenting rejection is warranted.

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

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are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-38 of U.S. Patent No. 5,503,614 ('614) to Liprie.

Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Upon review of the instant application claims and those of '614 the table below is presented to show how the claims in the instant application correspond with those in the patent, however only the rejection of claim 5 of the instant application is specifically explained below as exemplarily to how the other claims are also rejected.

<u>Application Claim Number</u>	<u>'614</u>
1,2,14,15,25	1,2,6,19,29,35
3,4,18,19	3,9

5-7,16,26	4,10,14,30
8,17,27	15,21,31
9,11,20, 21,28,29	1,19,29
10,22,30	7,8,27,37
12,23,31	16,22,32
13,24,32	17,23,33

Claim 5 of this application is rejected under the judicially created doctrine of "obviousness-type" double patenting over exemplary claim 4 of US Patent No. 5,503,614. A rejection based upon "obviousness-type" double patenting is based upon the judicially created doctrine grounded in public policy so as to prevent the unjustified or improper timewise extension of the right to exclude granted by the patent no matter how the extension is brought about and has, as its basis, the principles now well-established in Office practice, enunciated in In re Lonardo, 43 USPQ 2d 1262 (Fed. Cir. 1997); In re Goodman, 29 USPQ 2d 2010 (Fed. Cir. 1993); In re Berg, 6 USPQ 2d 1226 (Fed. Cir. 1998); In re Lilly, 58 USPQ 2d 1865 (Fed. Cir. 2001); In re Longi, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 214 USPQ 761 (CCPA 1982); In re Vogel, 164 USPQ 619 (CCPA 1970); and In re Thorington, 163 USPQ 644 (CCPA 1969).

Initially, it should be noted that

- (1) the instant application is a voluntarily filed application that may be related to application Serial No. 08/257,045, now Patent No. 5,503,614 (see figures 1-3);
- (2) the filing of the instant application was not necessitated by a restriction requirement;
- (3) there is a common relationship of inventorship and/or ownership of the patent and application (i.e., Samuel F. Liprie is the inventor in both the application and patent and United States Surgical Corporation is the assignee in each);
- (4) there is common disclosure supporting the application claims and the patent claims;
- (5) the application claims were never earlier presented;
- (6) this is not a case of an improvement or modification invented after filing of the parent application; and
- (7) the claims of the application are directed to the same embodiment as the claims in patent, i.e., to the embodiment of the source wire illustrated in Figures 1-3 of the patent.

As stated previously, the rule against double patenting seeks to prevent the unjustified extension of the right to exclude granted by a patent. Thus, the question to be answered is whether or not the subject matter covered by claim 13 of the patent would have its term extended if claim 1 in this application is patented. A side-by-side comparison of exemplary patent claim 13 with

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application claim 1 shows the following: Patent claim 13 and application claim 1 are directed to the same subject matter, i.e., a source wire comprising: an elongated housing tube; a flexible backbone wire; and a radiation means. However, application claim 1 differs from exemplary patent claim 13 in that the application claim has been:

- (1) broadened by reciting that the elongated housing is "a hollow, elongated housing tube" as opposed to "a hollow elongated housing tube having an outer surface, an interior surface and said proximal end having an inner surface",
- (2) narrowed by reciting "a radiation source or sources provided within the housing tube with the proximal end of the flexible backbone wire adjacent to the source or sources" as opposed to "a radiation device provided within and included within a sealing device wherein said radiation device is in proximity to said rounded end of said backbone wire",
- (3) broadened by reciting "a radiation source or sources" as opposed to "a radiation device",

Thus, upon overlaying application claim 1 onto patent claim 13, it is clearly evident that application claim 1 encompasses subject matter previously claimed in patent claim 13. The previously noted decisions by the CAFC, i.e., In re Goodman, supra, In re Berg, supra, In re Lilly, supra, and In re Lonardo, supra, set forth the doctrine of "obviousness-type double patenting" as follows:

- (1) Goodman - a later genus (broader) claim is not patentable over an earlier species (narrower) claim;
- (2) Berg - rejection of genus (broad) claims in a later patent application for obviousness-type double patenting proper in light of species (narrower) claims in an earlier patent;
- (3) Lonardo - invalidates claims in a later patent under doctrine of obviousness type double patenting where "alleged differences in elements are in species-genus form," with the earlier patent claiming elements more specifically and the later patent claiming elements more generally; and
- (4) Lilly - affirms that a later patent claim is not patentable over an earlier patent claim when a recited limitation in the later claim is an inherent characteristic, i.e., "a natural result" flowing from the reference's explicitly explicated limitation.

Comparing the application claim changes (noted hereinabove) relative to the patent claim by considering corresponding individual limitations and applying the appropriate rationale in Goodman, Berg, Lonardo and Lilly, the following analysis is appropriate:

- (1) Application claim elongated housing tube_{br} (genus) anticipated by patent claim elongated housing tube_{sp} (species) for reasons set forth in the Goodman, Berg and Lonardo decisions;
- (2) application claim adjacent flexible backbone_{sp} (species) anticipated by patent claim proximate flexible backbone_{br} (genus) for

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reasons set forth in the Goodman, Berg and Lonardo decisions further claim 35 of '614 clearly discloses that the source is adjacent the flexible backbone;

(3) application claim radiation source or sources_{br} (genus) anticipated by patent claim radiation device_{sp} (species), for reasons set forth in the Goodman, Berg and Lonardo decisions; and

Accordingly, the differences in subject matter between exemplary patent claim 13 and application claim 1 are such that the claims are not patentably distinct, i.e., the claims are deemed to be merely obvious variations. Thus, the application claim may not be properly issued in the absence of a terminal disclaimer.

Terminal Disclaimer

12. Examples of acceptable language for making the disclaimer of the terminal portion of any patent granted on the subject application follow:

I. If a Provisional Obviousness-Type Double Patenting Rejection Over A Pending Application was made, use:

The owner, _____, of _____ percent interest in the instant application hereby disclaims the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending **reference** Application Number _____, filed on _____, as such term is defined in 35 U.S.C. 154 and 173, and as the term of any patent granted on said **reference** application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending **reference** application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the **reference** application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

II. If an Obviousness-Type Double Patenting Rejection Over A Prior Patent was made, use:

The owner, _____, of _____ percent interest in the instant application hereby disclaims the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of **prior patent No.** _____ as the term of said **prior patent** is defined in 35 U.S.C. 154 and 173, and as the term of said **prior patent** is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

Alternatively, Form PTO/SB/25 may be used for situation I, and Form PTO/SB/26 may be used for situation II; a copy of each form may be found at the end MPEP § 1490.

Conclusion

13. Examiner's Note: Examiner has cited particular columns and line numbers in the references as applied to the claims for the convenience of the applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply as well. It is respectfully requested from the applicant, in preparing the responses, to fully consider the references in entirety as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the examiner.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel L. Greene Jr. whose telephone number is (571) 272-6876. The examiner can normally be reached on Mon-Fri 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jack Keith can be reached on (571) 272-6878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DIG
2006-02-13

JACK KEITH
SUPERVISORY PATENT EXAMINER